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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,395	12/30/2003	Robert C. Farnan	0341-0053.01	7559

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EXAMINER

AHMED, AAMER S

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,395	FARNAN, ROBERT C.	
	Examiner	Art Unit	
	Aamer S. Ahmed	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>08/08/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species Group A (Figure 1) and electing claims 1-16 reading on this species, in the reply filed on January 6, 2006 is acknowledged.

Drawings

The drawings are objected to because the elements are not clearly discernable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Claim 11 is objected to because of the following informalities: the phrase “at a selected keep open rate” is unclear. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Gianturco U.S. Patent Number 4,445,896.

As to claim 1, Gianturco discloses a vascular catheter lumen patency device comprising a fluid chamber (18) for containing a fluid under pressure; a valve member (17) for controlling the flow of fluid into the chamber, and an outlet (21) from the chamber (18) adopted to communicate with the lumen of an indwelling vascular catheter.

As to claims 4-7 and 11, Gianturco discloses that the device comprises a self-sealing port (col. 2 line 60) in the valve (17) member; formed of an elastomeric material (col. 3 line 56); and

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further comprising a male luer lock (12), with a through passageway (21) therein communicating with the fluid chamber (18); and comprising a female luer lock connector (13), wherein the female luer lock is connected to said male luer lock (13); and wherein the outlet (21) includes a port sized to allow fluid flow to flow from the fluid chamber (18) at a selected keep open rate (see figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 3 and 12-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Gianturco in view of Aalto et al U.S. Patent Number 4,597,758.

Gianturco discloses the device as described above in reference to claim1, and further discloses that the device defines at least three regions, a first region for receiving said valve

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member, a second region being the fluid chamber, and a third region (see figure 1); a cap (16) an elastomeric plug (17) located at the first end of the cap body a fluid storage chamber (18) located adjacent to the elastomeric plug (17) in the cap body (16); and a through hole (21) located at the second end of the cap body (16) and adjacent to said fluid storage chamber (18), wherein the fluid storage chamber is filled with a fluid, further comprising a port (21) located at the first end of the cap body (16) and located in the plug (17) wherein the elastomeric plug seals itself after introduction of the fluid; and wherein the through hole (21) is located within a male luer lock (12); and further comprising a female luer lock (13), wherein the female luer lock (13) and the male luer lock (12) combine to prevent fluid from exiting the second end of the cap (16) when the cap is not in use.

Gianturco fails to disclose a fluid permeable filter in the third region.

Aalto et al discloses a similar device with a fluid permeable filter (26). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Gianturco by incorporating the filter of the kind taught by Aalto et al in order to restrict the flow of fluid.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gianturco in view of Doyle U.S. Patent Number 6,290,206. Gianturco discloses the device as described above in reference to claim 1.

Gianturco fails to disclose that fluid N₂.

Doyle discloses a similar device in which N₂ is used to pressurize a chamber (col. 11 line 29)

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Gianturco by incorporating N₂ gas in the fluid chamber as taught by Doyle in order supplement the normal resiliency of plug (col. 11 line 29).

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gianturco and Aalto et al in view of Doyle.

Gianturco and Aalto et al discloses the device as described above in reference to claim 12.

Gianturco and Aalto et al fail to disclose that fluid N₂.

Doyle discloses a similar device in which N₂ is used to pressurize a chamber (col. 11 line 29)

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Gianturco by incorporating N₂ gas in the fluid chamber as taught by Doyle in order supplement the normal resiliency of plug (col. 11 line 29).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6007521 A	Bidwell; Robert E. et al.
US 3868973 A	Bierman; Howard R. et al.
US 6213986 B1	Darling, Jr.; Phillip H.
US 20040102738 A1	Dikeman, W. Car y et al.
US 4718893 A	Dorman; Frank D. et al.
US 4772263 A	Dorman; Frank D. et al.

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US 6695817 B1	Fangrow, Jr.; Thomas F.
US 6537268 B1	Gibson; Scott R. et al.
US 4838887 A	Idriss; Samir F.
US 6932795 B2	Lopez; George A. et al.
US 6428520 B1	Lopez; George A. et al.
US 3620500 A	Louis S. Santomieri
WO 9735141 A1	MELOUL, RAPHAEL F et al.
US 6170800 B1	Meloul; Raphael F. et al.
US 5205834 A	Moorehead; H. Robert et al.
US 5843046 A	Motisi; Paul J. et al.
US 3338548 A	MOTT LAMBERT H
US 5954698 A	Pike; Kevin H.
US 4604090 A	Reinicke; Robert H.
US 5080652 A	Sancoff; Gregory E. et al.
US 4245636 A	Sparks; Sam L. et al.
US 5599296 A	Spears; James R.
US 20040181191 A1	Teitelbaum, George P.
US 20020010442 A1	Teitelbaum, George P.
US 5290263 A	Wigness; Bruce D. et al.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A. Ahmed


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